

**REMARKS/ARGUMENTS**

Upon entry of the instant amendment, claim 1 will be amended, and claims 21-25 will be added, whereby claims 1-25 will be pending. Claim 1 is the sole independent claim.

Applicant notes that claim 1 has been amended to clarify that the cap further comprises at least one protrusion on one of the first cap member and second cap member, the at least one protrusion being capable of engaging and disengaging at least one stop on the other of the first cap member and the second cap member as the first cap member and the second cap member are rotated relative to each other, and at least one of the at least one protrusion and the at least one stop being located within the threads of one of first cap member and the second cap member.

Moreover, claims 21-25 have been added to further define, as recited in claims 21, that each of said at least one protrusion and said at least one stop are located in the threads of the first cap member and the second cap member; as recited in claim 22, that the at least one protrusion is fixed on the one of the first cap member and the second cap member; as recited in claims 23 and 24, that the at least one stop is fixed on the other of the first cap member and the second cap member; and as recited in claim 25, that the at least one protrusion is composed of resilient material.

Support for the claim amendments appears throughout Applicant's specification, drawings and claims, including page 16, lines 17-25.

**Information Disclosure Statement**

Applicant expresses appreciation for the forwarding with the Office Action of an initialed copy of the Form PTO-1449 submitted with the Information Disclosure Statement, filed September 7, 2001.

Upon review of the initialed copy of the form, it is noted that Canadian 523,078 and Sutor et al. are marked "Not Available" and are not initialed. Applicant is therefore submitting additional copies of these documents which were previously submitted and considered by the Examiner during prosecution of the parent application. Moreover, Applicant is submitting another Form PTO-1449 listing these documents. The Examiner is therefore respectfully requested to initial this form, and to forward an initialed copy of the form with the next communication from the Patent and Trademark Office.

**Response to Formal Matters**

Applicant expresses appreciation for the acknowledgment of the claim of domestic priority under 35 U.S.C. 120 and/or 121.

**Response To Obviousness-Type Double Patenting Rejection**

(a) Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-26 of U.S. Patent No. 6,346,114. In this ground of rejection it is asserted, without indicating any basis for the assertion, that although the

conflicting claims are not identical, they are not patentably distinct from each other because they include substantially the same structural limitations in the claims of the same invention.

In response, Applicant respectfully submits that if this ground of rejection is maintained in order to advance prosecution of the application, and without expressing any agreement or acquiescence to the rejection of record, an executed Terminal Disclaimer will be submitted. The submission of the executed Terminal Disclaimer will be submitted solely to advance the application to issue. In this regard, if this is the only outstanding issue remaining in the application upon consideration of the present response, the Examiner is respectfully requested to contact the undersigned by telephone for submission of an executed Terminal Disclaimer.

#### **Response To Indication Of Allowable Subject Matter And Rejections Based Upon Prior Art**

Applicant expresses appreciation for the indication that claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

However, Applicant respectfully submits that each of the pending claims is allowable over the prior art of record, whereby each of the pending claims should be indicated to be allowable. Therefore, an early mailing of the Notices of Allowance and Allowability is respectfully requested.

The following rejections are set forth in the Office Action:

(a) Claims 1-3,6,8-12,14-15 and 18-20 rejected under 35 U.S.C. 102(e) as being anticipated by Morita, U.S. Patent No. 5,730,753.

In this ground of rejection, it is asserted that Morita (Figs. 1-5) shows an penetration depth adjusting assembly for use with an injector (col. 4, line 62 to col. 5, line 11) having a housing, a needle holding member, a biasing element, a trigger and an adjusting cap assembly including 2<sup>nd</sup> cap 3 and 1<sup>st</sup> cap 5&7. 2<sup>nd</sup> cap 3 includes threads 17, stop/recess 39/projection 37. 1<sup>st</sup> cap 5&7 includes threads 53 engaging threads 17 of 2<sup>nd</sup> cap 3, interior stops or protrusions or nipple 57 engaging recess 39 of 2<sup>nd</sup> cap 3. The depth of penetration of the injector is asserted to be adjusted by rotation of 1<sup>st</sup> cap 5&7 relative to 2<sup>nd</sup> cap 3.

(b) Claims 4-5, 7, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morita, U.S. Patent No. 5,730,753, as applied to claim 1 above, and further in view of Cyktich, U.S. Patent No. 5,509,345.

In this ground of rejection, it is asserted that Morita discloses substantially all limitations in the claims except for grooves/ridges on thread portion and spring-biased balls as protrusions. It is asserted that Cyktich discloses balls 48 biased by spring 56 to engage in grooves 64. In view of Cyktich, it is asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide grooves in the threads 17 of 2<sup>nd</sup> cap 3 and replace protrusion 57 by a spring-biased ball to engage threads 17 as this would be another choice of design.

In response, Applicant notes that independent claim 1 is directed to a lancet device, comprising:

- a housing;

- a needle holding member in the housing for holding a lancet;

- a biasing element for biasing the needle holding member toward an extended position;

a trigger for releasing the needle holding member from a retracted position; and

a cap for covering the housing and for positioning the lancet device relative to a skin surface, the cap comprising a first cap member having threads and a second cap member having threads, the cap further comprising at least one protrusion on one of the first cap member and second cap member, the at least one protrusion being capable of engaging and disengaging at least one stop on the other of the first cap member and the second cap member as the first cap member and the second cap member are rotated relative to each other, and at least one of said at least one protrusion and said at least one stop being located within the threads of one of first cap member and the second cap member.

Initially, with regard to the anticipation rejection based upon Morita, Applicant respectfully submits that Morita does not teach each and every element recited in Applicant's independent claim 1, whereby claim 1 and each claim dependent therefrom is not properly rejectable based upon Morita. In particular, Morita is directed to an assembly for adjusting pricking depth of lancet. Morita discloses beginning at column 11, line 66, that the cap element 3 has the peripheral step portion 37 which is adjacent to the thread portion 17, and the step portion includes at least one recess portion (for example groove) 39 for clicking. The recess portion has a shape and a size which allow the protruding portion 57 provided onto the adjusting element 5 to fit into the recess portion 39 so as to achieve clicking. Morita discloses that the adjusting element 5 and the cap element 3 are in an engagement state with clicking at a predetermined rotation position so that a user easily recognizes that a desired pricking depth has been set.

Thus, is it apparent that Morita does not disclose, amongst other features recited in

Applicants' claims, a cap for covering the housing and for positioning the lancet device relative to a skin surface, the cap comprising a first cap member having threads and a second cap member having threads, the cap further comprising at least one protrusion on one of the first cap member and second cap member, the at least one protrusion being capable of engaging and disengaging at least one stop on the other of the first cap member and the second cap member as the first cap member and the second cap member are rotated relative to each other, and at least one of said at least one protrusion and said at least one stop being located within the threads of one of first cap member and the second cap member.

Thus, the anticipation rejection of the originally presented claims as well as Applicant's amended claims is without appropriate basis, and should be withdrawn.

With respect to the obviousness rejection based upon Morita in view of Cyktich, Applicant respectfully submits that it would not have obvious for one having ordinary skill in the art to combine the diverse disclosures of Morita and Cyktich, and that even if for the sake of argument the disclosures were combined Applicant's disclosed and claimed invention would not be at hand.

As noted above, Morita discloses an assembly for adjusting pricking depth of lancet wherein step portion 37 which is adjacent to the thread portion 17 is structured and arranged to provide adjustment. In an attempt to overcome the deficiencies of Morita, the rejection relies upon Cyktich. However, Cyktich is directed to non-analogous art, and one having ordinary skill in the art would not look to the disclosure of Cyktich to modify the lancet of Morita. In particular, Cyktich is directed to a muzzle attachment for improving firearm accuracy. Certainly one having ordinary

skill in the art would not look to a muzzle attachment for improving firearm accuracy to modify a lancet. In this regard, there must be motivation in the prior art to make the asserted combination.

As set forth in MPEP 2141.01(a), in order to rely upon a reference under 35 U.S.C. 103, the reference must be analogous prior art. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

In discussing analogy in the mechanical arts, this section of the MPEP points to a number of cases. Of the cases discussed in the MPEP, a case that appears to be particularly pertinent with regard to Cyktich being nonanalogous prior art which does not support an obviousness rejection is the above-noted Oetiker case. In particular, it is noted that Applicant claimed an improvement in a hose clamp which differed from the prior art in the presence of a preassembly "hook" which maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened. The MPEP notes that the Board relied upon a reference which disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous. The MPEP further notes that the court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments.

Similarly to Oetiker, Applicant respectfully submits that Cyktich is not reasonably pertinent to the particular problem with which the present inventor was concerned, because there is no indication that a person of ordinary skill in the art seeking to solve a problem of adjusting penetration depth of a lancet device would reasonably be expected or motivated to look to muzzle attachments for improving firearm accuracy.

Thus, Applicant respectfully submits that one having ordinary skill in the art would not look to Cyktich. Moreover, one having ordinary skill in the art would not be motivated to modify Morita with the disclosure of Cyktich in view of the structural characteristics and different materials of construction associated with the diverse products in these two documents. Moreover, even if for the sake of argument Morita was modified with the disclosure of Cyktich, such modification be made with respect to portion 37 and not to threads 17.

The rejection merely supports the asserted modification by making a naked assertion of design choice. However, a mere assertion of design choice is not a proper rejection. What must be established is why one having ordinary skill in the art would make such design choice, and why the asserted design choice would be effected at the asserted location when Morita specifically discloses other structure in another location for achieving his intended adjustable lancet. The Examiner is reminded that the structure of a primary reference cannot be essentially destroyed when combining references. The rejection must include motivation for making an asserted design choice modification.

Additionally, each of the dependent claims is patentable over the cited documents in view of the fact that each of these dependent claims includes the recitations of independent claim 1.



Moreover, each of the dependent claims is patentable over the cited documents because it would not have been obvious to a skilled artisan to incorporate such dependent claim features into the invention as more broadly recited in independent claim 1.

For example, Cyktich fails to disclose or suggest at least one protrusion fixed on one of the first member and the second member. In this regard, Applicant respectfully submits that a skilled artisan would understand that detent balls 46, 48 would be free to rotate as the relative position of the adapter 12 and the member 14 is changed. Further, CYKTICH discloses that the detent balls 46, 48 are installed and removed via gap d4, (col. 4, lines 54-55). Still further, a skilled artisan would understand that detent balls 46, 48 would be able to move radially outward to a certain extent since the detent balls 46, 48 are held in gap d4 by spring ring 56. Thus, detent balls 46, 48 would not be fixed on either adapter 12 or member 14, because detent balls 46, 48 are not stationary with respect to either adapter 12 or member 14.

Thus, claim 2 further patentably defines that the at least one stop comprises at least one recess.

Claim 3 further patentably defines that the least one stop comprises at least one projection.

Claim 4 further patentably defines that the threads of the other of the first member and the second member comprise a groove and a ridge, and wherein the at least one stop is located in the groove.

Claim 5 further patentably defines that the threads of the other of the first member and the second member comprise a groove and a ridge, and wherein the at least one stop is located in the ridge.

Claim 6 further patentably defines that the at least one protrusion comprises a nipple.

Claim 7 further patentably defines that the at least one protrusion comprises a spring-biased ball.

Claim 8 further patentably defines that the at least one protrusion is on an interior of the cap.

Claim 9 further patentably defines that the at least one protrusion comprises a plurality of protrusions.

Claim 10 further patentably defines that the first cap member comprises a surface for aligning the lancet device on skin of a patient, the surface having an opening for a needle in the needle holding member to pass through, and wherein the at least one protrusion is on the second cap member.

Claim 11 further patentably defines that the first cap member comprises a surface for aligning the lancet device on skin of a patient, the surface including an opening for a needle in the needle holding member to pass through, and wherein the at least one protrusion is on the first cap member.

Claim 12 further patentably defines that a length of the cap is adjustable by rotation of the first cap member relative to the second cap member for adjusting a penetration depth of a needle in the needle holding member.

Claim 13 further patentably defines that the at least one protrusion is connected to a button for releasing the at least one protrusion from the at least one stop.

Claim 14 further patentably defines that the at least one protrusion is biased into the at least one stop.

Claim 15 further patentably defines that the first cap member and the second cap member are rotatable relative to each other in both a clockwise and a counter-clockwise direction.

Claim 16 further patentably defines that each of the at least one protrusion is formed on one of a single groove and a single ridge of the threads of one of the first cap member and the second cap member; wherein when one of the at least one protrusion is formed on a said single groove of one of the first cap member and the second cap member, a corresponding at least one stop is formed on a ridge of the threads of the other of the first cap member and the second cap member; and wherein when one of the at least one protrusion is formed on a said single ridge of one of the first cap member and the second cap member, a corresponding at least one stop is formed on a groove of the threads of the other of the first cap member and the second cap member.

Claim 17 further patentably defines that the at least one stop is in the threads.

Claim 18 further patentably defines that the at least one protrusion is fixed on the one of the first cap member and second cap member.

Claim 19 further patentably defines that the at least one stop is fixed on the other of the first cap member and the second cap member.

Claim 20 further patentably defines that the at least one protrusion is fixed on the one of the first cap member and second cap member, and wherein the at least one stop is fixed on the other of the first cap member and the second cap member.

Claim 21 further patentably defines that each of said at least one protrusion and said at least one stop are located in the threads of the first cap member and the second cap member.

Claim 22 further patentably defines that the at least one protrusion is fixed on the one of the first cap member and the second cap member.

Claims 23 and 24 further patentably define that the at least one stop is fixed on the other of the first cap member and the second cap member.

Claim 25 further patentably defines that the at least one protrusion is composed of resilient material.

Accordingly, the anticipation and obviousness rejections should be withdrawn.

### **CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejection of record, and allow all the pending claims.

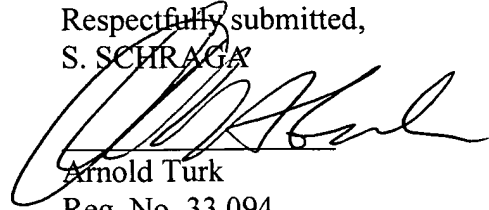
Allowance of the application is requested, with an early mailing of the Notices of Allowance and Allowability.

P21072.A06

Application No. 09/874,992

If the Examiner has any questions or wish to further discuss this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,  
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